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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 08/11/2004

Cahill, von Hellens & Glazer P.L.C.
Ste. 155
2141 E. Highland Avenue
Phoenix, AZ 85018

EXAMINER	
PATEL, NIHIR B	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 08/11/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,797	09/04/2003	Gregory S. Marler	3418-A-23	8070

TITLE OF INVENTION: HEAT AND MOISTURE FILTER EXCHANGER AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$300	$965	11/12/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 07/04) Approved for use through 04/30/2007.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,797	09/04/2003	Gregory S. Marler	3418-A-23	8070

TITLE OF INVENTION: HEAT AND MOISTURE FILTER EXCHANGER AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$300	$965	11/12/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
PATEL, NIHIR B	3743	128-918000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1_____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2_____ 3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ❑ individual ❑ corporation or other private group entity ❑ government

4a. The following fee(s) are enclosed:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s):

❑ A check in the amount of the fee(s) is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is not claiming SMALL ENTITY status. See, e.g., 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

(Authorized Signature) (Date)

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DATE MAILED: 08/11/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 07/04) Approved for use through 04/30/2007.

Notice of Allowability	Application No.	Applicant(s)	
	10/654,797	MARLER ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Juky 12th, 2004*.

2. ☒ The allowed claim(s) is/are *1-13*.

3. ☒ The drawings filed on *09.04.2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Henry Bennett
Supervisory Patent Examiner
Group 3700

DETAILED ACTION

Election/Restrictions

Applicant's arguments filed on July 12th, 2004 have been fully considered and are persuasive. Claim 1 is generic and does read on all species.

Reason for Allowance

The following is an examiner's statement of reasons for allowance: Claims 1 through 13 of application number 10/654797 are allowable over the prior art of record in that the heat and moisture exchanger for selectively conducting a stream of air produced by a ventilator through a moisturizing medium or causing the stream of air to bypass the moisturizing medium, the heat and moisture exchanger comprises a housing having a ventilator-side port configured to be coupled to an outlet of a ventilator and a source of aerosolized medication, the housing also having a patient-side port configured to be coupled to a patient to provide ventilation to the patient; a structure within the housing forming a first path within the housing for conducting non-aerosolized air from the ventilator-side port through the moisturizing medium to the patient-side port and a second path within the housing for conducting air carrying aerosolized medication from the ventilator-side port to the patient-side port by bypassing the moisturizing medium; and a two way valve mechanism in the housing for selectively coupling the ventilator-side port into fluid communication with one or the other of the first and second paths.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NP
July 30th, 2004

Henry Bennett
Supervisory Patent Examiner
Group 3700

Notice of References Cited	Application/Control No. 10/654,797	Applicant(s)/Patent Under Reexamination MARLER ET AL.	
	Examiner Nihir Patel	Art Unit 3743	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,992,413	11-1999	Martin et al.	128/201.13
	B	US-5,906,201	05-1999	Nilson, Billy	128/203.16
	C	US-5,647,344	07-1997	Turnbull, Christopher Stratton	128/201.13
	D	US-5,590,644	01-1997	Rosenkoetter, Terry G.	128/201.13
	E	US-5,462,048	10-1995	Lambert et al.	128/201.13
	F	US-5,460,172	10-1995	Eckerbom et al.	128/201.13
	G	US-5,022,394	06-1991	Chmielinski, Mark A.	128/207.14
	H	US-4,771,770	09-1988	Artemenko et al.	128/201.13
	I	US-4,327,717	05-1982	Oetjen et al.	128/201.13
	J	US-4,318,398	03-1982	Oetjen et al.	128/201.13
	K	US-4,090,513	05-1978	Togawa, Tatsuo	128/201.13
	L	US-6,745,766	06-2004	Fini, Massimo	128/204.17
	M	US-4,016,878	04-1977	Castel et al.	128/202.26

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	0 409 402 A1	01-1991	Great Britian	Kanegaonkar	A61M 16/00
	O	0 265 163 A2	04-1988	Great Britian	Wallace	A61M 16/10
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 10/654,797	Applicant(s)/Patent Under Reexamination MARLER ET AL.	
	Examiner Nihir Patel	Art Unit 3743	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-D301,377	05-1989	Lambert, Hans R.	D24/164
	B	US-5,577,494	11-1996	Kuypers et al.	128/201.13
	C	US-4,621,632	11-1986	Bartels et al.	128/203.27
	D	US-5,005,569	04-1991	Pasternack, Adalbert	128/204.13
	E	US-6,588,421	07-2003	Diehl et al.	128/201.13
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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USPTO TO PROVIDE ELECTRONIC ACCESS TO CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS AND CEASE SUPPLYING PAPER COPIES

In support of its 21st Century Strategic Plan goal of increased patent e-Government, beginning in June 2004, the United States Patent and Trademark Office (Office or USPTO) will begin the phase-in of its E-Patent Reference program and hence will: (1) **provide downloading capability of the U.S. patents and U.S. patent application publications cited in Office actions** via the E-Patent Reference feature of the Office's Patent Application Information Retrieval (PAIR) system; and (2) **cease mailing paper copies of U.S. patents and U.S. patent application publications with Office actions** (in applications and during reexamination proceedings) except for citations made during the international stage of an international application under the Patent Cooperation Treaty (PCT). In order to use the new E-Patent Reference feature applicants must: (1) obtain a digital certificate and software from the Office; (2) obtain a customer number from the Office; and (3) properly associate patent applications with the customer number. Alternatively, copies of all U.S. patents and patent application publications can be accessed without a digital certificate from the USPTO web site, from the USPTO Office of Public Records, and from commercial sources. The Office will continue the practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of cited references will continue to be provided by the USPTO for international applications during the international stage.

Schedule

June 2004	TCs 1600, 1700, 2800 and 2900
July 2004	TCs 3600 and 3700
August 2004	TCs 2100 and 2600

All U.S. patents and U.S. patent application publications are available on the USPTO web site. However, a simple system for downloading the cited U.S. patents and patent application publications has been established for applicants, called the E-Patent Reference system. As E-Patent Reference and Private PAIR require participating applicants to have a customer number, retrieval software and a digital certificate, all applicants are strongly encouraged to contact the Patent Electronic Business Center to acquire these items. To be ready to use this system by June 1, 2004, contact the Patent EBC as soon as possible by phone at 866-217-9197 (toll-free), 703-305-3028 or 703-308-6845 or electronically via the Internet at ebc@uspto.gov.

Other Options

The E-Patent Reference function requires the applicant to use the secure Private PAIR system, which establishes confidential communications with the applicant. Applicants using this facility must receive a digital certificate, as described above. Other options for obtaining patents which do not require the digital certificate include the USPTO's free Patents on the Web program (http://www.uspto.gov/patft/index.html). The USPTO's Office of Public Records also supplies copies of patents for a fee (http://ebiz1.uspto.gov/oems25p/index.html). Commercial sources also provide U.S. patents and patent application publications.

For complete instructions see the Official Gazette Notice, USPTO TO PROVIDE ELECTRONIC ACCESS TO CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS AND CEASE SUPPLYING PAPER COPIES, on the USPTO web site.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 409 402 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 90306397.2

(51) Int. Cl.5: **A61M 16/00**, B01D 46/52

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(30) Priority: 18.07.89 GB 8916361

(43) Date of publication of application:
23.01.91 Bulletin 91/04

(84) Designated Contracting States:
DE ES FR IT SE

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London NW11 8DS(GB)

(54) Heat and moisture exchange devices.

(57) A heat and moisture exchanger has an element 4 formed by a strip of bacterial filter material that is folded laterally into pleats and bent into a loop so that the folds 41 and 42 extend radially. The element 4 is sealed around its outer edge into a circular casing 1 having axial, tapered ports 2 and 3 at opposite end. A conical gas diverter 46 and 47 is sealed into a central opening of the element 4 on each side. Exhaled gas warms and moistens the element 4; inhaled gas is filtered and takes up some of the heat and moisture from the element. The exchanger is symmetrical so that it can be used either way around.

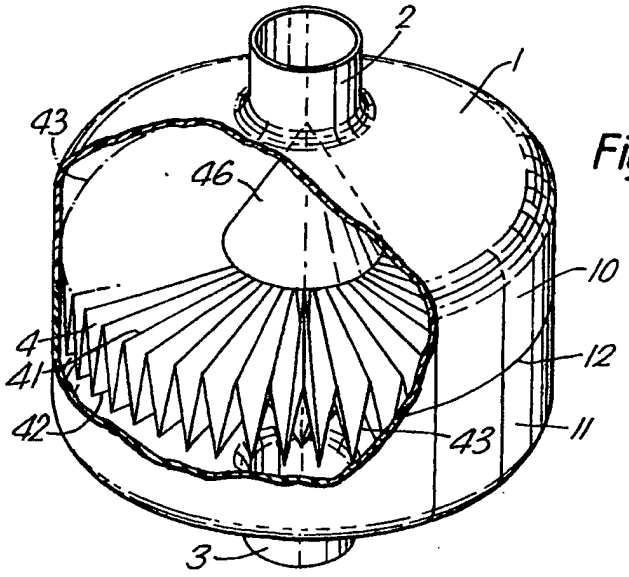


Fig.1.

EP 0 409 402 A1

HEAT AND MOISTURE EXCHANGE DEVICES

This invention relates to heat and moisture exchange devices of the kind for transferring heat and moisture in exhaled respiratory gas to inhaled respiratory gas including an outer casing and an exchange element within the outer casing.

Heat and moisture exchange devices are used in medico-surgical applications to take up heat and moisture from a patient's exhaled breath passing through the device and to transfer it to inhaled gas. One disadvantage with the presently available exchange devices, is that they impede the flow of the gas, leading to a pressure drop across the exchange element. This pressure drop can be reduced by increasing the area of the element exposed to the gas. This, however, makes the element larger and heavier, thereby correspondingly increasing the size and weight of the housing which may cause discomfort to the patient. It can also increase the dead space within the casing and increases the cost of the device itself, its packaging, transport and storage. Some devices must be connected in a particular orientation in order to prevent the build up of condensation in the device. This is a disadvantage because it requires care to be taken by the user in connecting the device into the patient breathing circuit.

It is an object of the present invention to provide a heat and moisture exchange device that can be used to alleviate the above-mentioned problems.

According to one aspect of the present invention there is provided a heat and moisture exchange device of the above-specified kind, characterised in that the exchange element comprises a strip of material folded into a plurality of pleats laterally of the length of the strip, and that the strip is bent into a loop such that the folds of the pleats extend radially of the loop in two parallel planes substantially normal to the direction of flow of respiratory gases through the element.

The opposite ends of the strip are preferably joined together. The loop may have a central opening with a gas diverter mounted therein to divert gas onto the exchange element. The exchange element is preferably sealed around its outer edge in the casing by a settable sealing compound. The outer casing may be of circular section, the exchange element being located axially within the casing with the planes of the folds of the pleats extending transversely of the casing, and the casing having a first port arranged axially on one side of the element and a second port arranged axially on the other side of the element. The casing may have a tapered port at each end which communicates with a respective side of the exchange element.

The exchange element is preferably made of a filter material, the exchange element being arranged in the casing such that gas flowing through the device is filtered. The filter material is preferably a bacterial filter material.

According to another aspect of the present invention there is provide a method of making a heat and moisture exchange device, characterised in that the method comprises comprising the steps of: folding a strip of material laterally at equal intervals in opposite senses to form pleats; compressing the pleats into a pack such that adjacent pleats contact one another, the pack having two opposite faces between which the folds of the pack extend; sealing together adjacent pleats on one face; pulling opposite end folds of the pack from adjacent the other face around the one face to form a loop with the folds of the pleats extending radially; joining the opposite end folds together; filling any space at the centre of the loop; inserting the loop into a casing; and sealing the outer edge formed by the other face of the pack with the inside of the casing such that exhaled warm, moist gas flowing through the device in one direction flows through the material and a part of the heat and moisture is retained by the material, whereas inhaled gas flows through the material in the opposite direction and is warmed and moistened by the retained heat and moisture.

The adjacent pleats on the one face are preferably sealed together by coating the one face with a flexible, settable sealing compound.

A heat and moisture exchange device for medical ventilation gases, and its method of manufacture, in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of the exchange device;

Figure 2 is a sectional side elevation view of the exchange device; and

Figures 3 to 6 illustrate steps in the manufacture of a part of the exchange element.

The heat and moisture exchange device comprises a moulded plastics casing 1 with an inlet port 2 and an outlet port 3, the casing containing an exchange element 4.

The casing 1 is moulded in two parts 10 and 11, from a hard plastics material such as nylon or PVC, which are joined together along a circumferential split line 12. The casing 1 is of cylindrical shape and circular section with the inlet 2 and outlet 3 located axially in line which communicate with opposite sides of the element 4. The inlet 2

and outlet 3 are conventional luer taper or anaesthetic taper fittings and may be male, female or of a universal form incorporating a coaxial arrangement of a male and female coupling.

The exchange element 4 is made of a high efficiency, bacterial filtration medium such as a glass fibre membrane treated with a silicone oil, such as Syloff AVA sold by the Whatman Paper Company.

The exchange element 4 takes up heat and moisture in exhaled breath passing through the element 4 and transfers it to gas passing through the element in the opposite direction. The element 4 is permeable to gases but impermeable to bacteria and viral particles either by sieving these bacteria and particles from the gas stream or by providing a tortuous path through the element which causes these and other particles to be impeded upon the surface of the element because their greater momentum prevents them from circumnavigating the fibres of the element. In this respect, the element also acts as a filter as well as a heat and moisture exchange element.

The element 4 is in the form of a pleated circular loop of filter material with the folds 41 and 42 of the pleats extending radially. The folds 41 lie in a plane transverse to the direction of flow through the device as indicated by the arrows F; the opposite folds 42 lie in a plane parallel to that including the folds 41 but located closer to the outlet 3 of the device. The outer edge 43 of the exchange element 4 is sealed to the inner surface of the casing 1 such that there is no path for gas flow between the exchange element and the casing. In this respect, an adhesive or settable sealing compound can be used.

The inner edge 44 of the exchange element 4 is sealed, with an adhesive or settable sealing compound, to a gas-impermeable core piece 45 which extends through the centre of the element and blocks passage of gas through the centre. The core piece 45 is a hollow moulding of a light plastics material which is cylindrical in shape and provided with two flow diverters 46 and 47 at opposite ends. Both diverters 46 and 47 are of conical shape with a base that overlaps the inner edge 44 of the upper and lower surface of the exchange element 4. The exchange device is, therefore, of symmetrical configuration. Instead of using a gas-impermeable core piece, this could be replaced with an element having filtering and heat and moisture exchange properties similar to those of the glass fibre membrane.

In use, the inlet 2 is connected to a ventilation circuit which may include ventilation or anaesthetic equipment or may simply be open to atmosphere. The lower outlet 3 is connected via tubing to a tracheal tube or breathing mask. When the patient inhales, gas enters the device in a downwardly direction (although the device can be used in any orientation) through the inlet 2 and is diverted radially outwardly by the upper diverter 46 onto the upper surface of the element 4. Pressure difference across the element 4 causes gas to flow through the inclined faces of the element between the folds 41 and 42 of the pleats. Gas passing through the exchange element 4 flows out of the device through the outlet 3. When the patient exhales, gas flows through the device in the opposite direction, from the outlet to the inlet.

By mounting a diverter 46 and 47 on both sides of the filter element 4 it enables the device to be used either way around, providing that the inlet and outlet couplings 2 and 3 are compatible with the connections to the device. This is an advantage because it means that no special care need be taken to ensure that the device is correctly oriented.

The exchange element 4 is preferably made in the manner shown in Figure 3 to 6. First, as shown in Figure 3, a strip of the filter material, which is typically 21mm wide and 2857mm long, is folded laterally at equal intervals in opposite senses to form fifty-one pleats each of length 56mm. The strip is then compressed into a pack so that adjacent pleats come into contact with one another in the manner shown in Figure 4. Next, the pleats on one face of the pack, which will eventually form the inner edge 44 of the exchange element 4, are sealed by coating the face with a flexible, settable sealing compound 50, as shown in Figure 5. The opposite end folds of the pack are then gripped close to the opposite face and pulled around, as shown in Figure 6, to form a loop. An adhesive is used to seal these end folds together. The element now formed resembles a ruff with the folds 41 and 42 of the pleats extending radially and with an outer diameter of 56mm, an inner diameter of 14mm and a thickness of 27mm. Prior to installation in the casing 1, the outer edge 43 of the element is sealed and coated with a similar compound to that applied to the inner edge 44. The element 4 is preferably installed in the casing 1 before the sealing compound is set, so that it conforms to the inner surface of the casing 1 and seals with it. The core piece 45 with the flow diverters 46 and 47 are mounted on the exchange element 4 before installation in the casing.

Because the folds 41 and 42 of the exchange element 4 extend radially, the average separation between the pleats is greater than in previous exchange elements employing axially arranged pleats. This gives the device a more open construction thereby admitting more gas to the element which in turn allows more gas to pass through the entire element and reduces the resis-

tance to flow provided by the element. In this way, the size of element can be smaller than that of a conventional exchange element having the same resistance to flow. The exchange device of the present invention can, therefore, be made smaller and lighter than previous device or with reduced resistance to flow.

Claims

1. A heat and moisture exchange device for transferring heat and moisture in exhaled respiratory gas to inhaled respiratory gas including an outer casing, and an exchange element within the casing, characterised in that the exchange element (4) comprises a strip of material folded into a plurality of pleats laterally of the length of the strip, and that the strip is bent into a loop such that the folds (41, 42) of the pleats extend radially of the loop in two parallel planes substantially normal to the direction of flow of respiratory gases through the element (4).

2. A device according to Claim 1, characterised in that the opposite ends of the strip are joined together.

3. A device according to Claim 1 or 2, characterised in that the loop has a central opening (44) with a gas diverter (45, 46, 47) mounted therein to divert gas onto the exchange element (4).

4. A device according to any one of the preceding claims, characterised in that the exchange element (4) is sealed around its outer edge (43) in the casing (1) by a settable sealing compound.

5. A device according to any one of the preceding claims, characterised in that the outer casing (1) is of circular section, that the exchange element (4) is located axially within the casing (1) with the planes of the folds (41, 42) of the pleats extending transversely of the casing (1), and that the casing (1) has a first port (2) arranged axially on one side of the element and a second port (3) arranged axially on the other side of the element.

6. A device according to any one of the preceding claims, characterised in that the casing (1) has a tapered port (2, 3) at each end which communicates with a respective side of the exchange element (4).

7. A device according to any one of the preceding claims, characterised in that the exchange element (4) is made of a filter material, and that the exchange element is arranged in the casing such that gas flowing through the device is filtered.

8. A device according to Claim 7, characterised in that the filter material is a bacterial filter material.

9. A method of making a heat and moisture exchange device, characterised in that the method comprises comprising the steps of: folding a strip of material laterally at equal intervals in opposite senses to form pleats; compressing the pleats into a pack such that adjacent pleats contact one another, the pack having two opposite faces (43 and 44) between which the folds (41 and 42) of the pack extend; sealing together adjacent pleats on one face (44); pulling opposite end folds of the pack from adjacent the other face (43) around the one face (44) to form a loop with the folds (41 and 42) of the pleats extending radially; joining the opposite end folds together; filling any space at the centre of the loop; inserting the loop into a casing (1); and sealing the outer edge (43) formed by the other face of the pack with the inside of the casing (1) such that exhaled warm, moist gas flowing through the device in one direction flows through the material and a part of the heat and moisture is retained by the material, whereas inhaled gas flows through the material in the opposite direction and is warmed and moistened by the retained heat and moisture.

10. A method according to Claim 9, characterised in that the adjacent pleats on the one face (44) are sealed together by coating the one face with a flexible, settable sealing compound (50).

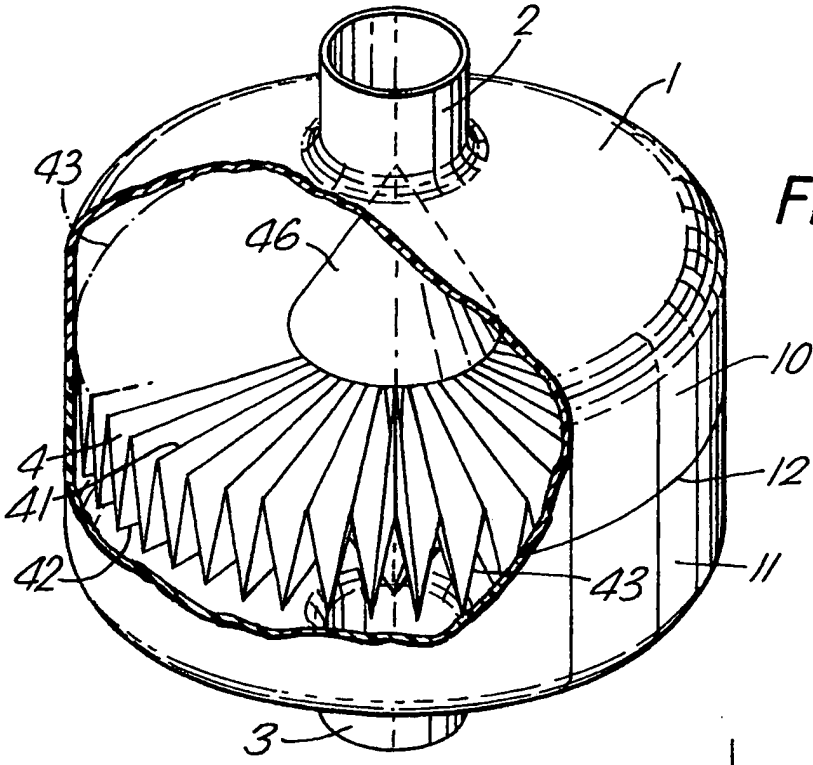

2
1
43
46
10
4
41
12
42
43
11
3

Fig.1.

Fig.2.

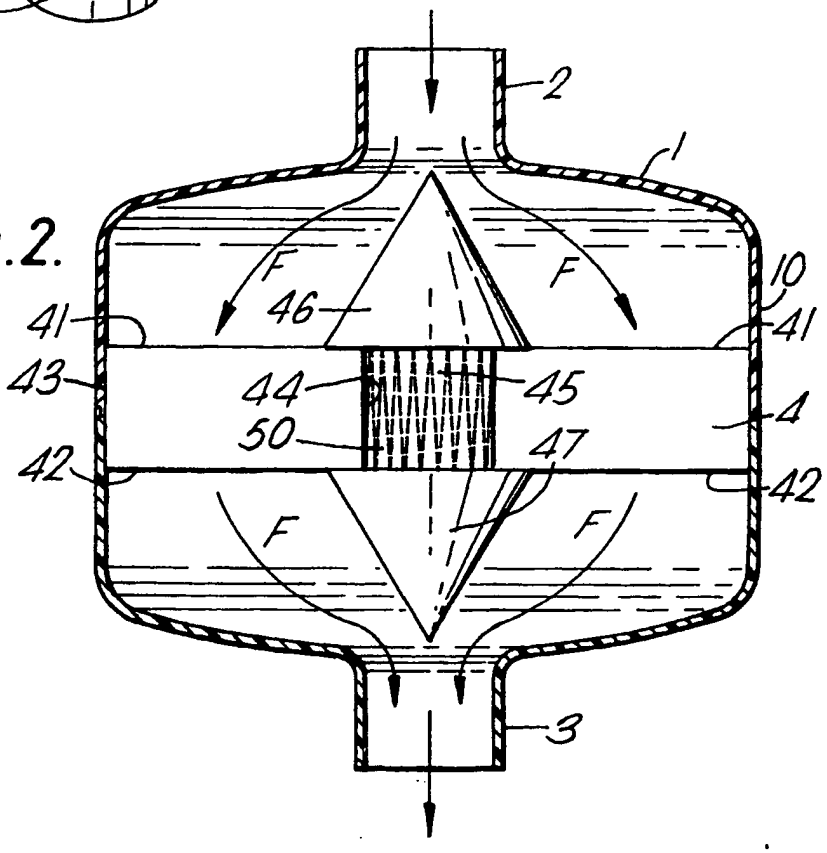

2
1
F
F
46
10
41
41
43
44
45
4
50
47
42
42
F
F
3

Fig.3.

Fig.4.

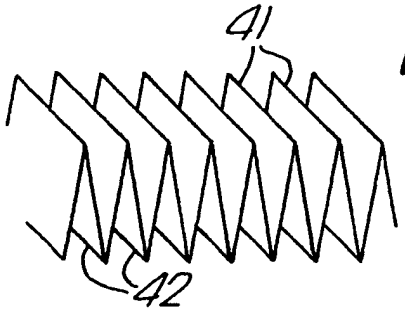


Fig.5.

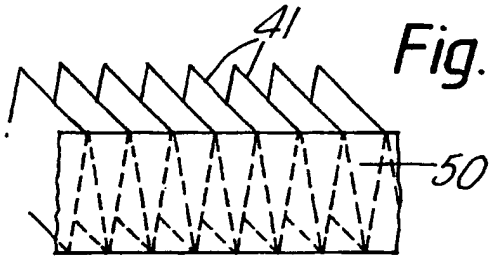
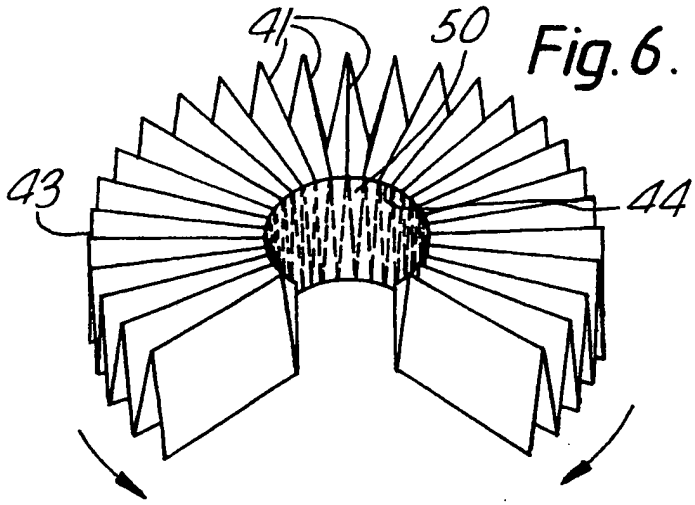


Fig.6.



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 90 30 6397

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	EP-A-0 205 072 (TERUMO K.K.) * Claims *	1	A 61 M 16/00 B 01 D 46/52
Y	US-A-3 803 817 (R.D. LEWIS) * Drawings; column 2, line 20 - column 4, line 25 *	1	
A		2,3,4,5,7,9,10	
A	US-A-4 619 675 (M. WATANABE) * Column 2, line 12 - column 3, line 11; drawings *	1,2,4,5,7	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 M
B 01 D

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17-10-1990	BOGAERTS M.L.M.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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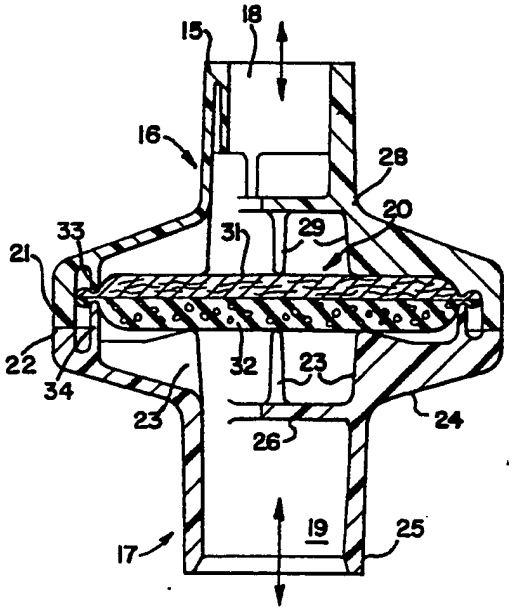
(54) Heat and moisture exchanger.

(57) This disclosure relates to a heat-moisture exchanger comprising first and second parts which are secured together to form a hollow housing. Ports are formed in the housing for connection to a patient and to a source of breathable gas, and the hollow interior of the housing forms a passageway for inhalation and exhalation gases to and from the patient. An insert is mounted within the housing and across the passageway, and comprises first and second materials. The first material forms a large surface area for the exchange of heat and moisture by condensation and evaporation. The second material is hydrophilic and absorbs moisture and then releases it by evaporation. The insert further acts as a filter of bacteria and virus.

FIG-3



EP 0 265 163 A2

Field and Background of the Invention

This invention relates to a combination heat and moisture exchanger and filter for use in respiratory care and anesthesiology systems.

When a person is breathing in a normal manner through the nose or mouth, the inhaled air or other gas is warmed and humidified by the tissues of the mouth, nose and pharynx. By the time the gas reaches the bronchial tubes it is normally at body temeprature and at about 99% humidity.

However, when a patient is connected in a respiratory care system and a tracheal or tracheostomy tube is inserted into the trachea the gas is fed directly into the bronchial tubes. The gas thus bypasses the tissues and it is not adequately warmed and humidified. If the inhaled gas entering the bronchi is dry and cool, there will be a heat and moisture loss from the tracheal mucosa, causing it to dry and thicken and produce breathing problems.

Devices have been provided in the past to add heat and moisture to the inhaled gas. Humidifiers and vaporizors for this purpose are usually relatively expensive and require attention to the water supply and to the temperature and humidity controls.

An alternative to humidifiers and vaporizors as described above is a heat and moisture exchanger (HME). An exchanger contains an insert which removes heat and moisture from exhaled gas and then returns at least part of the heat and moisture to the subsequently inhaled gas. One type of exchanger collects moisture by condensation on the surfaces of the insert during exhalation and releases moisture by evaporization during inhalation.

A heat exchange process also occurs during operation of such an exchanger. Some heat is lost by convection through the walls of the tubes and the exchanger. Further, the heat of condensation is given up by the moisture to the walls of the exchanger (where some is lost), and the heat of vaporization is taken by the moisture from the walls.

In addition to the foregoing prior art, the following patents relate to breathing systems:

U.S.:

443,191
3,491,754
3,814,094
3,932,153
3,941,862
4,063,913
4,133,656
4,171,962
4,318,398

British:

2,053,694

Patent No. 443,191 shows an air filter including cotton/wool soaked with medicine or glycerine. No. 3,491,754 shows a breath warmer including layers of foam, metal foil and nylon mesh. No. 3,814,,094 shows a breath warmer including layers of aluminum screen and foam rubber. No. 3,932,153 shows a bacteria filter including a disk of porous Teflon impregnated with micro glass fiber on one side and nylon or glass cloth on the other side. The disk has its edge clamped between two housing parts. No. 3,941,862 shows a gas diffuser for use in a humidifier. No. 4,063,913, No. 4,133,656 and No. 4,171,962 show a bacteria filter including filter paper. No. 4,318,398 shows a humidity exchanger including vapor permeable fiber tubes. British No. 2,053,694 shows an exchanger including tubular fibers.

It is a general object of this invention to provide an improved heat and moisture exchanger which is also a bacterial and viral filter.

Summary of the Invention

Apparatus in accordance with this invention comprises first and second housing parts which are secured together to form a hollow housing. Ports or openings are formed in the housing for connection to a patient and to a source of breathable gas, and the hollow interior of the housing forms a passageway for inhalation and exhalation gases flowing to and from the patient. An insert is mounted within the housing and

across the passageway, and comprises first and second materials. The first material forms a large surface area for the exchange of heat and moisture by condensation and evaporation. The second material is hydrophilic and absorbs moisture and then releases it by evaporation. The insert further acts as a filter of bacteria and virus.

Brief Description of the Drawings

The foregoing and other objects and advantages of the present invention will become apparant from the following detailed description taken in conjunction with the accompanying figures of the drawing, wherein:

Fig. 1 is an illustration of an exchanger in accordance with the invention in use by a patient;

Fig. 2 is an enlarged exploded view of the exchanger;

Fig. 3 is a sectional view of the exchanger;

Fig. 4 is a view taken on the line 4-4 of Fig. 2; and

Fig. 5 is a view taken on the line 5-5 of Fig. 2.

Detailed Description of the Drawings

Fig. 1 shows a heat and moisture exchanger 10 in use by a patient indicated generally by the numeral 11. An endotracheal tube 12 is connected between an adaptor 9 and the patient, the tube 12 extending into the trachea of the patient, and the adaptor is connected to the exchanger. The other side of the exchanger 10 is connected to the center leg of a Y-piece 8, the other two legs of the Y-piece being connected by tubes 14 to a machine 13 such as an anesthesia gas or ventilation machine which is designed to supply a breathable gas to the patient 11. The gas may be oxygen or an anesthetic, for example. During such use, both the inhaled and the exhaled gases flow through the exchanger 10. During exhalation, a portion of the heat and the moisture of the exhaled gas is removed from the gas by the exchanger 10, and during inhalation, heat and moisture are transferred from the exchanger 10 to the gas prior to inhalation by the patient.

The heat and moisture exchanger 10 comprises first and second housing parts 16 and 17, which are generally funnel-shaped and have outer walls 28 and 24. The part 16 has an opening 18 formed at its small diameter end 15, this end 15 being adapted to be connected to the adaptor 9 and the endotracheal tube 12. Similarly, the other part 17 has an opening 19 formed in its small diameter end 25 which is adapted to be connected to the Y-piece 8 and the gas machine 13. The two units 16 and 17 further have large diameter ends 21 and 22, respectively, which are positioned against each other and secured together. The two housing parts may be formed of molded polyethylene and are secured together by such means as sonic welding. The housing parts 16 and 17 thus form a hollow interior which serves as a passageway for gas flowing between the two openings 18 and 19, and an insert 20 is mounted across the passageway.

With specific reference to Figs. 3 and 5, the section of the part 17 shown in Fig. 3 is taken on the line B-B of Fig. 5. The interior of the part 17 has four interior ribs which extend radially inwardly from the outer wall 24 to the diameter of the smaller opening 19, the ribs 23 being provided to strengthen the wall 24. In addition, a diagonally extending rib or brace 26 extends across the opening 19, which prevents a connecting tube from being inserted excessively far into the housing. The rib 26 also creates air turbulance within the housing and thereby increases the efficiency of the exchanger.

Similarly, the section of the part 16 shown in Fig. 3 is taken on the line A-A of Fig. 4. The housing part 16 includes a plurality of radially extending ribs 27 which extend from the wall 28 to the interior diameter of the opening 18. Intermediate shorter ribs 29 may also be formed on the interior of the wall 28. Another diagonal rib 31 may be formed on the interior of the housing part 16 and extend across the opening 18, the rib 31 having the same function as the rib 26.

The insert 20 is disk-shaped and is formed by two side-by-side layers 31 and 32. The two layers 31 and 32 have essentially the same outer diameter, and this diameter is slightly less than the diameters of the large ends 21 and 22 of the two housing parts. Circular pinch rings 33 and 34 are also formed at the large ends 21 and 22 and are spaced radially inwardly a short distance from the outermost edges of the housing parts. The circular pinch ring 33 of the part 16 is recessed axially inwardly from the lower edge of the large diameter end 21, whereas the pinch ring 34 of the other part 17 extends upwardly a short distance out of the large diameter open end 22. When the ends 21 and 22 are butted against each other as shown in Fig. 3, the adjacent ends of the two pinch rings 33 and 34 are spaced a short distance apart and the outer

periphery of the insert 20 is located between these adjacent ends, and as shown in Fig. 3, the pinch rings 33 and 34 tightly grip the outer periphery of the insert 20 and hold it in place. In addition, the ribs 23 and 29 of the two housing parts are closely adjacent the opposite sides of the insert 20 and prevent excessive movement of the insert.

While a specific example of a material for the housing and a method of assembling the housing parts are described, it should be understood that the invention encompasses other lightweight housing materials and methods of assembly.

The layer 31 of the insert 20 is formed of natural polypropylene fibers having a close weave or mesh. The fibers are permanently electrostatically charged and thus also form a bacterial and viral filter. Such material is commercially available for this purpose, and a layer having a weight of approximately 200 grams per square meter is preferred. A heavier (and therefore thicker or more dense) material such as 300 grams per square meter may produce an excessive pressure drop for a given flow rate of gas. On the other hand a lighter material such as 100 grams per square meter may not have sufficient surface area. The other layer 32 is an open-cell urethane plastic foam which is pretreated to absorb moisture. A suitable hydrophilic foam is sold by the Scott Foam Company under the trademark Acquell, and this type of foam can absorb approximately 30 times its weight in moisture. The foam releases moisture by evaporation when dry gas from the machine 13 flows through it to the patient. It is preferred that foam having a thickness of approximately 1/4 inch be used, and such a layer produces virtually no pressure drop even though it absorbs a large amount of moisture.

To manufacture the exchanger shown in the drawings, the two housing parts 16 and 17 are formed and the two layers 31 and 32 are cut to size and positioned adjacent each other. In one mode of assembly, the housing part 16 is positioned with the large diameter end 21 facing upwardly and the two layers 31 and 32 are positioned within the open end 21. The outer periphery of the insert 20 is substantially equal to the interior diameter of the wall 28 at the large diameter end 21. As shown in Fig. 3, the diameter of the insert 20 is slightly greater than the diameters of the pinch rings 33 and 34, and the insert 20 is positioned with its outer periphery on the pinch ring 33. The other part 17 is then positioned over the open end 21 and the two pinch rings 33 and 34 pinch and grip the outer periphery of the insert. The ends 21 and 22 are then secured together by means such as an ultrasonic welding process, as previously mentioned.

In the use of the unit, the end 15 is connected to the adaptor and the endotracheal tube 12 and the end 25 is connected to the Y-piece 8. When the exhaled gas passes through the tubes and through the exchanger 10, the layers 31 and 32 collect moisture. The fiber layer 31 has a large surface area and moisture in the gas is condensed on the fiber surfaces. In addition, the treated foam layer 32 absorbs moisture as the exhaled gas passes through it. Some of the moisture condensed on the fibers is transferred to and absorbed by the foam layer 32 because of the close side-by-side relation of the layers 31 and 32, thereby increasing the effectiveness of both layers. Some of the moisture also condenses on the interior surfaces of the two housing parts 16 and 17. As the moisture condenses, the latent heat of condensation in the moisture is released and it warms the layers and the housing. When the patient inhales, the gas moves in the other direction through the housing and into the patient 11. The moisture in the two layers 31 and 32 is released and evaporated by the dry gas, and the gas is also warmed by the exchanger.

In addition, the fiber layer 31 serves as a filter and traps bacteria and virus (and other particles) both during inhalation and during exhalation.

It will be apparent from the foregoing that a novel and useful heat and moisture exchanger and filter has been provided. There are a number of factors that should be considered in the design of a heat and moisture exchanger. First, the exchanger should have sufficient size and capacity to add the needed amount of heat and moisture to the air flowing to the patient. However, the second and third factors limit the size of the exchanger. The second factor is that the exchanger should be small and lightweight because it is often supported by the patient on the tracheal tube. Third, its interior should be small because the dead space in the housing should be kept to a minimum. In the specific example illustrated and described herein, the diameter of the ends 21 and 22 is substantially 6.3 cm, and the total dead space within the housing is substantially 40 cc. Still another factor is that the pressure drop, or the resistance to air flow, across the exchanger should be as low as possible so that it does not hinder the patient's breathing.

The exchanger described herein meets these conflicting requirements. The two layers of the insert cooperate to exchange an adequate amount of heat and moisture even though they are relatively small in diameter and thin. There is little pressure drop across the foam layer and the fiber layer is thin enough that it does not significantly obstruct breathing. The parts of the exchanger are relatively small and are made of lightweight materials. Further, the ribs within the housing parts create gas turbulance which distributes the gas flow throughout the insert. In addition, the insert operates as a filter in addition to its other functions.

Claims

1. A heat-moisture exchanger comprising a housing forming a hollow interior and having two flow openings formed therein, said interior and said openings forming a two directional gas flow passage through said housing between said openings, and an insert mounted in said housing and extending across said passage, said insert comprising a first layer of fibers forming a bacterial and viral filter, and a second layer of a hydrophilic material, each of said layers having substantially flat sides and positioned in close side-by-side relation with said flat sides extending across and perpendicular to said gas flow passage, said flat sides being in mutual contact, and all of said gas flowing through said insert in both directions of gas flow.

2. A heat-moisture exchanger according to Claim 1, wherein said first layer comprises of polypropylene fibers.

3. A heat-moisture exchanger according to Claim 2, wherein said second layer comprises an open-cell urethane plastic foam and means to enhance absorption of moisture.

4. A heat-moisture exchanger according to Claim 1, wherein said housing comprises first and second parts each having one of said flow openings therein, said first and second parts being secured together and clamping said insert between them.

5. A heat-moisture exchanger according to Claim 4, wherein said first and second parts of said housing have pinch rings formed thereon, and said insert is clamped between said pinch rings.

6. A heat-moisture exchanger according to Claim 1, wherein said housing has ribs formed therein, said ribs strengthening said housing and at least some of said ribs causing turbulance of gas flowing through said insert.

Fig. 1

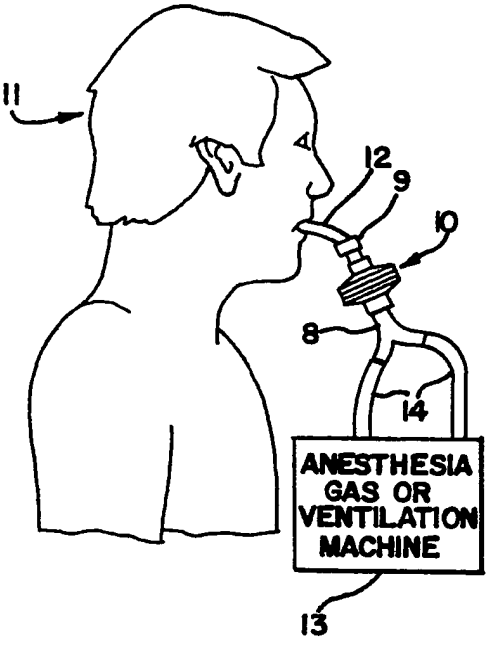


Fig. 2

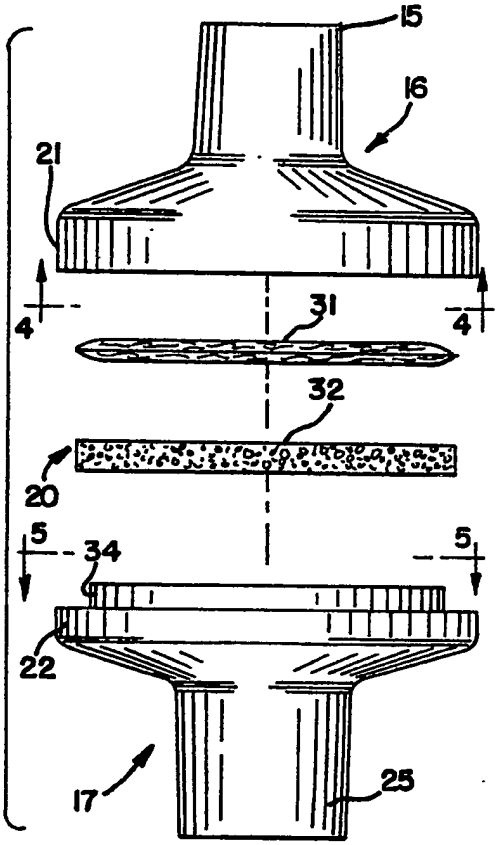


Fig. 3

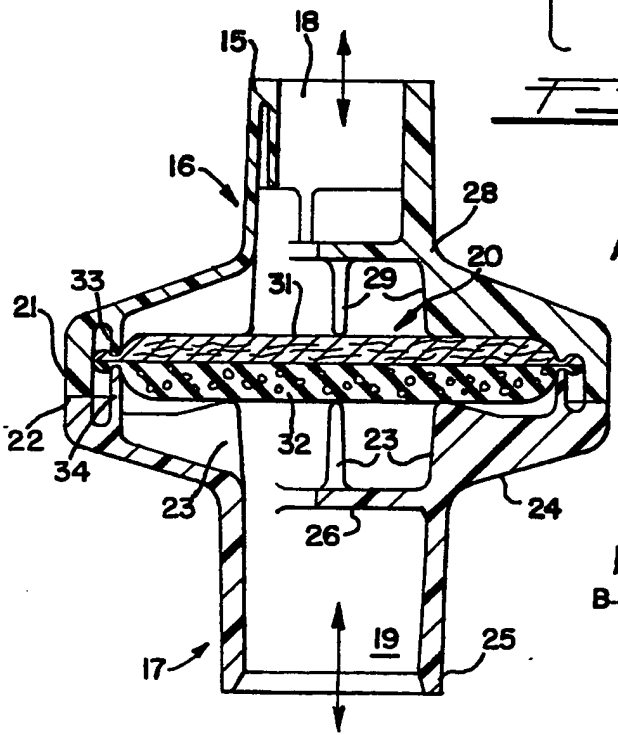


Fig. 4

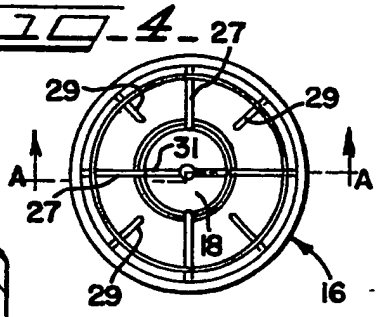
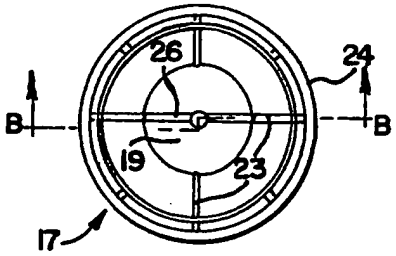


Fig. 5



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